UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Julie Breeden-Alemi, DVM

From: Tim Ciarlo, MS, Entomologist

Secondary Review: Pesticide Efficacy Review Committee (PERC)

Date: October 3, 2017

Subject: PRODUCT PERFORMANCE PROTOCOL REVIEW

THIS PROTOCOL REVIEW DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 442313
Decision no.: 532517
Submission no: 1007801
Action code: R272
Product Name: Thermacell Mosquito Repellent
EPA Reg. No: 71910-2
Formulation Type: Spatial Repellent
Ingredients statement from the label with PC codes included:

d-Allethrin	21.97%	PC: 004005

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 or mg/kg body weight as appropriate): EPA Reg No. 71910-2 includes two different sized mats, which release d-allethrin upon heat-activation. The smaller mat is designed to repel mosquitoes from a 225 ft^2 area for up to 4 hours, while the larger mat is designed to repel mosquitoes from a 225 ft^2 area for up to 12 hours.

Use Patterns: Heat-activated outdoor spatial repellent

I. Action Requested: Risk Manager requests review of a protocol to determine if it may generate acceptable efficacy data for the 4-hour mat to support claims of repels mosquitoes which may transmit the Zika virus.

II. Background: Field efficacy data were recently reviewed by the Agency (DP 432851) and found to be unacceptable to support any claims against mosquitoes which may transmit Zika virus. Although *Aedes* spp. mosquitoes were collected in the field trials, none of the trapped mosquitoes included *Aedes aegypti* or *Ae. albopictus*. Since the latter two species are the predominant vectors of Zika virus, claims making reference to mosquitoes which may transmit Zika virus could not be supported. This protocol describes a field study intended to produce efficacy data which might be adequate to support repellency claims against mosquitoes which may transmit Zika virus.

Repellency claims against mosquitoes are supported for this product for both the 4-hour and 12-hour mats (DP

421168). However, there are currently no acceptable efficacy data on file against *Ae. aegypti* or *Ae. albopictus* specifically.

III. MRID Summary:

50360601. 2017. Mosquito spatial repellent efficacy test protocol.

(1) This protocol describes a GLP study.

(2) **General Comments:**

EPA Reg No. 71910-2 includes two different sized mats. The smaller one is designed to repel mosquitoes from a 225 ft^2 area for up to 4 hours, while the larger mat is designed to repel mosquitoes from a 225 ft^2 area for up to 12 hours. However, the protocol described in MRID 50360601 proposes to only test the 4-hour mat in a field setting with known populations of *Ae. aegypti* or *Ae. albopictus* so that the claim of "repels mosquitoes" can be expanded to "repels mosquitoes which may transmit Zika virus." Since the registration includes both mat sizes, the Agency suggests repellency be evaluated using both the 4-hour and 12-hour mats. This will avoid a situation in which the label for 71910-2 states that the product "repels mosquitoes which may transmit Zika virus for 4 hours" while simultaneously stating that it "repels mosquitoes for 12 hours." These claims appearing simultaneously on the label for 71910-2 would be misleading for consumers.

It is not necessary to collect trap data for the entire 12-hour burn duration. The 12-hour mats could be "turned on" for 8 hours elsewhere, then taken to field sites for evaluation over the course of the final 4 hours. If adequate repellency is demonstrated for the final 4 hours, it is reasonable to assume that the 12-hour mats are effective for the entire 12 hours. An alternative approach would consist of submitting product chemistry data which show that the same amount of d-allethrin is released from the 12-hour mat at the end of the 12-hour burn time compared with the end of the 4-hour burn time for the 4-hour mats. If this equivalency can be adequately demonstrated, there would be no need to include the 12-hour mat in field evaluations. Efficacy data generated with the 4-hour mats could be bridged to support the 12-hour mats as well.

The Agency is agreeable to the proposed minimum trapping threshold of 5 *Ae. aegypti* and/or *Ae. albopictus* mosquitoes per hour. Data analysis should include all mosquito species trapped, not just the two aforementioned species. A minimum percent reduction in treated plots of 75% relative to the controls should be demonstrated for repellency claims to be supported.

(3) **Conclusion: Partially Acceptable.** This protocol is largely modeled on the non-human spatial repellent protocol which the Agency has been disseminating to interested parties as the standard method for assessing outdoor mosquito spatial repellent products. MRID 50360601 is acceptable provided the comments in this document are addressed in protocol amendments and included in the final study report. Acceptance of this protocol does not guarantee the outcome of the generated data as "acceptable." The results presented in the final study report will be reviewed in the context of the protocol and the proposed labeling.

IV. Note to reviewer/PM:

Any data generated from subsequent studies described by this protocol are intended to supplement the existing efficacy data suite supporting EPA Reg No. 71910-2. They will not necessarily support mosquito repellency claims as standalone studies.